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(54) **Pharmaceutical compositions containing Lactobacillus brevis and Lactobacillus salivarius for
treatment of vaginal infections**

Pharmazeutische Zusammensetzungen enthaltend Lactobacillus brevis und Lactobacillus salivarius
zur Behandlung von Vaginainfektionen

Compositions pharmaceutiques à base de Lactobacillus brevis et de Lactobacillus salivarius pour le
traitement d'infections du vagin

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(56) References cited:
EP-A- 0 353 581 WO-A-94/06416
GB-A- 2 261 372 US-A- 5 705 160

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Examples 10 to 15

[0058] Examples 4 to 9 were repeated following the same modalities as specified in said Examples respectively, with the only difference that a microbic-culture lyophilized product was used (concentration 1×10^{10} CFU/g) which consisted of *L. brevis* ATCC 14869, *L. salivarius* subsp. *salicinicus* ATCC 11742 and *L. gasseri* ATCC 9857 species in a 1:1:1 ratio.

5 [0059] All pharmaceutical preparations obtained in Examples 4 to 15 have proved to be very efficient in treating patients suffering from vaginosis and vaginitis.

10 **Claims**

1. Use of an association of lactobacilli of the *Lactobacillus brevis* and *Lactobacillus salivarius* subsp. *salicinicus* species for preparation of a pharmaceutical composition to be employed through vaginal administration for treatment of vaginosis and vaginitis.
- 15 2. A use as claimed in claim 1, in which said association of lactobacilli comprises one or more species of lactobacilli selected from *Lactobacillus salivarius* subsp. *salivarius*, *Lactobacillus jensenii*, *Lactobacillus catenaforme*, *Lactobacillus minutus* and *Lactobacillus gasseri*.
- 20 3. A use as claimed in claim 1, in which said association of lactobacilli consists of the *Lactobacillus brevis*, *Lactobacillus salivarius* subsp. *salicinicus* and *Lactobacillus gasseri* species.
4. A use as claimed in one or more of the preceding claims, in which said association of lactobacilli is employed at a concentration of 10^7 to 10^{13} CFU/g.
- 25 5. A use, as claimed in one or more of the preceding claims, in which the pharmaceutical composition is prepared in a liquid form, in the form of creams or ointments, or in a solid form, as pessaries or vaginal tablets.
- 30 6. A use as claimed in claim 5, in which the pharmaceutical composition is prepared in the form of tablets comprising at least two layers, both containing said species of lactobacilli, bound with usual excipients and additives, so that the release velocity of bacteria of the outermost layer is greater than the release velocity of bacteria of the innermost layer.
7. A pharmaceutical composition to be used through vaginal administration for treatment of vaginal infections, comprising an association of lactobacilli of the *Lactobacillus brevis* and *Lactobacillus salivarius* subsp. *salicinicus* species.
- 35 8. A composition as claimed in claim 7, in which said association of lactobacilli also comprises one or more species of lactobacilli selected from *Lactobacillus salivarius* subsp. *salivarius*, *Lactobacillus jensenii*, *Lactobacillus catenaforme*, *Lactobacillus minutus* and *Lactobacillus gasseri*.
- 40 9. A composition as claimed in claim 7, in which said association of lactobacilli consists of the *Lactobacillus brevis*, *Lactobacillus salivarius* subsp. *salicinicus* and *Lactobacillus gasseri* species.
10. A composition as claimed in one or more of claims 7 to 9, in which said association of lactobacilli is employed at a concentration of 10^7 to 10^{13} CFU/g.
- 45 11. A composition as claimed in one or more of claims 7 to 10, in a liquid form, in the form of creams or ointments, or in a solid form, as pessaries or vaginal tablets.
- 50 12. A composition as claimed in claim 11, in the form of tablets comprising at least two layers, both containing said species of lactobacilli, bound with usual excipients and additives, so that the release velocity of bacteria of the outermost layer is greater than the release velocity of bacteria of the innermost layer.

55 **Patentansprüche**

1. Verwendung einer Assoziation von Milchbakterien der Arten *Lactobacillus brevis* und *Lactobacillus salivarius* subsp. *salicinicus* zur Zubereitung einer pharmazeutischen Zusammensetzung zur vaginalen Verabreichung zur Be-



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Laktobasilleja sisältävät farmaseuttiset koostumukset emättimen tulehdusten hoitoon
Farmaceutiska sammansättningar som innehåller laktobaciller för behandling av slidans inflammationer

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